JUN - 4 2001

510K(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92"

SUBMITTER:	**Gambro Renal Products 10810 West Collins Avenue Lakewood, CO 80215 (303) 231-5075**
DATE PREPARED:	**February 19th, 2001**
DEVICE NAME:	**Gambro POLYFLUX 24S Capillary Dialyzer/Filter Labeled for Single Use & The Gambro POLYFLUX 24R Capillary Dialyzer/Filter Labeled for Multiple Use**
CLASSIFICATION NAMES:	**High Permeability Hemodialyzer / Hemofilter**
PREDICATE DEVICE:	**Gambro POLYFLUX 17S, 21S, 17R, & 21R Hemodialyzers/Filters Labeled for Single Use and Multiple Use**

Device Description:

Gambro POLYFLUX 24S & 24R Capillary Dialyzers/Filters Labeled for Single (24S) and Multiple Use (24R)

The Gambro POLYFLUX 24R, Capillary Dialyzer/Filter labeled for multiple use (reuse) and the Gambro POLYFLUX 24S, Capillary Dialyzer/Filter labeled for single use are identical in construction, performance, materials, design, intended use and function with the exception that one hemodialyzer is labeled for multiple use (24R) and the other is labeled for single use (24S). One product has the designation "**R**" indicating that it is intended for multiple use while the other has the designation "**S**" to designate that it is labeled for single use.

In addition, these two hemodialyzers are identical in design, materials, function and intended use to other Gambro POLYFLUX hemodialyzers which have been previously cleared by the FDA under 510(k) Notifications for both single and multiple use (510(k) Notifications K981414 (single use) and K994390 (multiple use)).

These devices are intended for use in hemodialysis and filtration for the treatment of acute and chronic renal failure and for certain types of intoxications for both single use and when reprocessed for reuse for a maximum of 15 reprocessing reuse cycles on the same patient.

If reprocessing and reuse is practiced, it is recommended that the reuse be done under the conditions as existed in the in vitro and confirmatory clinical studies undertaken by Gambro and presented in the labeling for this device. It may also be used in cases of acute fluid overload for the removal of plasma water. The membrane used in this device is identical to the membrane utilized in the Gambro POLYFLUX 17S, 17R, 21S, and 21R, Hemodialyzers /filters labeled for single use and multiple use and which have been previously cleared for marketing in the United States under 510K Notifications (K982414, K994390). A copy of these clearance letters is included in Section XI. E of this Notification.

Blood enters a blood inlet port where it is distributed to the hollow fibers. Each hollow fiber has an inner diameter of approximately 190 microns (wet hollow fiber internal diameter) and a wall thickness of 40 microns. The number of hollow fibers in each hemodialyzer / filter is 16,500 for the POLYFLUX 24R and 24S. This dialyzer has an effective membrane length of 250 mm. The effective membrane surface area is 2.4 square meters. The housing and end caps of this hemodialyzer / filter are made of polycarbonate. The fibers used in the Gambro POLYFLUX 24S and 24R are of the same composition as those previously approved for the Gambro POLYFLUX Hemodialyzers / Filters labeled for single use and multiple use (K982414 & K994390). The patient's blood traverses the inside of the hollow fibers and exits the device via a blood exit port.

By means of a hydrostatic pressure or transmembrane pressure which is created by a combination of positive and negative pressures across the membrane, plasma water along with certain lower molecular weight solutes pass through the membrane and into the dialysate or filtrate compartment of the device. Uremic toxins and waste products are removed from the patient's blood in this device by means of both diffusion and convection through the membrane and into the counter current flowing dialysis solution during hemodialysis. The dialysate exits the devices via a dialysate outlet port.

Predicate Devices:

The Gambro POLYFLUX 24S (single use) and 24R (multiple use), Capillary Dialyzers / Filters labeled for single and multiple use (reuse) respectively, are identical in design, materials, intended use and construction to the currently marketed Gambro POLYFLUX 17S, 17R, 21S, and 21R, Hemodialyzers / Filters, labeled for single and multiple use which have been cleared for marketing / sale in the United States under a 510K Notifications (K982414 for the Polyflux 17S and 21S and K994390 for the Polyflux 17R and 21R). Both the predicate and the proposed devices, incorporate an identical membranes and other blood contact materials. They are substantially equivalent to the listed predicate devices. The intended use for the proposed and predicate devices is also the same; hemodialyzer/ filter.

PREDICATE DEVICES

DEVICE NAMES	Gambro POLYFLUX 17S, & 21S, Hemodialyzer / Filter Labeled for Single use	Gambro POLYFLUX 17R & 21R Hemodialyzer / Filter Labeled for Multiple Use
INTENDED USE	Hemodialyzer/Filter	Hemodialyzer
510K NUMBER	K982414	K994390
APPROVAL DATE	3/26/99	10/26/2000

Intended Use:

POLYFLUX S Indications:

POLYFLUX S is intended for use in hemodialysis, hemodiafiltration, and hemofiltration for the treatment of chronic or acute renal failure.

The size, weight, state of uremia, cardiac status and general physical condition of the patient must be evaluated by the prescribing physician before each treatment. The choice of the appropriate capillary dialyzer/filter and associated equipment as well as the treatment operating parameters are the sole responsibility of the physician. Special attention must be paid in connection with pediatric use.

POLYFLUX S is not indicated for HDF in the USA.

POLYFLUX R Indications:

POLYFLUX R is intended for use in hemodialysis for the treatment of chronic or acute renal failure.

The choice of the filter is the responsibility of the physician. Special attention must be paid in connection with pediatric use.

CAUTION: If POLYFLUX R is reused, the procedure and disinfectant specified in the RENATRON INSTRUCTION MANUAL must be followed.

The POLYFLUX R may be reprocessed for reuse on the same patient.

This indication statement is essentially the same as the indication statement for the predicate devices.

Technological Characteristics:

Comparing the proposed devices to the predicate devices, they are substantially equivalent with the exception that the POLYFLUX 24S and 24R have a slightly larger effective membrane surface area compared to the predicate devices. Both the proposed and predicate devices use the same polyarylethersulfone, hollow fiber membrane. Both the proposed and predicate devices use polycarbonate for the housing and header material and polyurethane for the membrane potting material and are steam sterilized

Summary of Non-Clinical Tests:

In vitro data was collected according to the FDA Guidance for Hemodialyzer Reuse Labeling.

Clinical Test Results:

No clinical testing was performed

Conclusions:

Testing performed on the Gambro POLYFLUX 24S and 24R Capillary Dialyzers/Filters indicates that they are safe, effective, and perform as well as the predicate devices, when used in accordance with the instructions for use. In vitro and in vivo performance data and directions for reuse have been included in the labeling.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2001

Jeffrey R. Shideman, Ph.D.
Director, Therapy Group Americas
Gambro Renal Products
10810 W. Collins Avenue
LAKEWOOD CO 80215

Re: K010667
POLYFLUX 24S & 24R Capillary Dialyzer/Filter
for Single Use and Multiple Use
Dated: February 19, 2001
Received: March 6, 2001
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI and MSF

Dear Dr. Shideman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510 (k) NUMBER (IF *KNOWN*): *Not yet assigned*

DEVICE NAME: Gambro Polyflux 24R Capillary Dialyzer / Filter Labeled for Multiple Use (Reuse) and Gambro POLYFLUX 24S Capillary Dialyzer / Filter Labeled for Single Use

INDICATIONS FOR USE:

POLYFLUX S Indications:

POLYFLUX S is intended for use in hemodialysis, hemodiafiltration, and hemofiltration for the treatment of chronic or acute renal failure.

The size, weight, state of uremia, cardiac status and general physical condition of the patient must be evaluated by the prescribing physician before each treatment. The choice of the appropriate capillary dialyzer/filter and associated equipment as well as the treatment operating parameters are the sole responsibility of the physician. Special attention must be paid in connection with pediatric use.

POLYFLUX S is not indicated for HDF in the USA.

POLYFLUX R Indications:

POLYFLUX R is intended for use in hemodialysis for the treatment of chronic or acute renal failure.

The choice of the filter is the responsibility of the physician. Special attention must be paid in connection with pediatric use.

CAUTION: If POLYFLUX R is reused, the procedure and disinfectant specified in the RENATRON INSTRUCTION MANUAL must be followed.

The POLYFLUX R may be reprocessed for reuse on the same patient.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation **(ODE)**

Prescription Use ✓ OR Over-The-Counter-Use_____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010667